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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,909	02/14/2000	ANNIE MEINIEL	065691/0179	5643

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EXAMINER
CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/462,909	MEINIEL ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-24* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 8-15, 18, 19, 21, 23-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6,16,17,20 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1, 5 and 6 have been amended and claim 7 has been cancelled as requested in the amendment of Paper No. 20, filed on March 24, 2003. Claims 1-6 and 8-24 are pending in the instant application.

Claims 2-4, 9-10, 12, 14-15, 18-19, 21 and 23-24 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim, see reasons of record in section 3 of Paper No. 18. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 1, 5, 6, 8, 11, 13, 16-17, 20 and 22, in so far as they are directed to SEQ ID NOS 7 and 8 are under consideration.

2. Claim 1, as amended, is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 1 recites a composition comprising a peptide of SEQ ID NO: 9. As stated in communication of Paper No. 16, last paragraph, Applicant has elected SEQ ID NO: 7 as a single molecular embodiment of the peptide for examination. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1 and claims 8, 11 and 13, which depend from claim 1, are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 5, 6, 16, 17, 20 and 22 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on March 24, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Election/Restrictions

6. Applicant's traversal of the restriction requirement (pages 8-9 of the Response) has been carefully considered but is not deemed persuasive. The major disagreement appears to be if PCT or US restriction practice should be applied to the claims of instant application, which is a national stage of a PCT application. As it was fully explained earlier (see section 2 of Paper No. 18), because the elected protein comprising SEQ ID NO: 7, which is a species sequence of SEQ ID NO: 1, was known in prior art before the instant invention was made, it cannot serve as a unifying special technical feature. Accordingly, the claims are restricted based on the current US practice.

Applicant's request to consider "claims 3 and 4 as they read on the peptides of SEQ ID NOS: 7 and 8, which has been made clear by amending claims 5 and 6 to depend from claims 2 and 4, respectively" (page 9, second paragraph of the Response) is not persuasive because claims 3 and 4, as originally filed, do not recited elected sequences SEQ ID NO: 7 or 8.

Claim Objections

7. Claim s 5 and 6, as amended objected to because claims 5 and 6 depend from non-elected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 101

8. Claims 5, 6 and 16 stand rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter for reasons of record in section 7 of Paper No. 18. Applicant is advised that recitation of "a relatively short peptide which is not believed to occur in nature" (see arguments regarding amendment to claim 1 on page 10, second paragraph of the Response) is not sufficient to overcome this ground of rejection.

9. The Declaration of Gobron under 37 CFR 1.132 filed on March 24, 2003 is sufficient to overcome the rejection of claims 5, 6, 17, 20 and 22 under 35 U.S.C. 101 based upon the statement that administration of a peptide of SEQ ID NO: 8 leads to improvement in regeneration of nervous tissue *in vivo* after experimental spinal cord injury in rats.

Claim Rejections - 35 USC § 112

10. Claims 17 and 20 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement for reasons of record in section 11 of Paper No. 18 and reasons that follow. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Claims 17 and 20 are directed to a pharmaceutical composition comprising a peptide of SEQ ID NO: 8 and to a method for treating a pathological condition or trauma requiring regeneration of nervous system cells by administration to a patient an effective amount of peptide of SEQ ID NO: 8, respectively. However, the instant specification fails to provide enough guidance for one skilled in the art on how to practice the instant method, thereby requiring undue experimentation to discover how to use Applicant's invention, as currently claimed.

The nature of the invention as asserted in the instant specification and further supported in the Declaration of Gobron is that a peptide of SEQ ID NO: 8 when administered directly to disrupted spinal cord, leads to the improvement of regeneration of nervous tissue in rats. This finding appeared to be novel because it was not recognized in the art that peptide of SEQ ID NO: 8 is associated with regeneration of nervous tissue. The limited working examples in the specification, as originally filed, pertain to *in vitro* studies of the instant peptides and cell cultures. Thus, Applicant's invention is predicated on the assertion that peptide of SEQ ID NO: 8 would be useful in regeneration of nervous system cells. Applicant further develops this assertion into a method for treating a pathological condition or trauma requiring regeneration of nervous system cells. Accordingly, it would appear that Applicant provides a single finding (the finding), and then presents an invitation to experiment to determine the effective amount, as well as routes and regimes of administration of a peptide of SEQ ID NO: 8.

Moreover, the instant specification provides no guidance on how to practice the claimed method with any particular pathological condition or trauma requiring regeneration of nervous system cells. A skilled artisan would not reasonably believe that administration of a peptide of

SEQ ID NO: 8 to a patient would lead to treatment of any pathological condition or trauma in general, as broadly claimed in claim 20.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

"[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

In view of the lack of teachings and unpredictability of the art set forth earlier, and also the total absence of the working examples, the instant specification is not found to be enabling for a method for treating a pathological condition or trauma requiring regeneration of nervous system cells by administration of a peptide of SEQ ID NO: 8 or for a pharmaceutical composition comprising a peptide of SEQ ID NO: 8 . It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to use Applicants' invention as currently claimed.

11. Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons of record in section 14 of Paper No. 18. Specifically, the metes and bounds of the recitation "and 89-96" cannot be determined from the claim.

Claim Rejections - 35 USC § 102

12. Claims 5, 6, 16, 17 and 22 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gobron et al. for reasons of record in section 16 of Paper No. 18. Because of the use of open language in defining the structure of the claimed peptides and because Gobron et al. disclose a fragment of SCO-spondin, which has the amino acid sequence identical to SEQ ID NO: 8 of the instant application and also matches the description of SEQ ID NO: 7, Gobron et al. anticipate claims 5, 6, 16, 17 and 22.

Conclusion

13. No claim is allowed.

14. This application contains claims 2-4, 9-10, 12, 14-15, 18-19, 21 and 23-24 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 782-9306 for regular communications and (703) 782-9307 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original

signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. OC
May 21, 2003

JOHN ULM
PRIMARY EXAMINER
GROUP 1600